

# Patient safety and quality of healthcare in EU policies

**Basia Kutryba**

**EU Working Group on Patient safety and Quality of Care, Chair;  
ESQH Fellow; WHO Collaborating Center for Developing Quality  
and patient Safety in Health Systems, Krakow, Head**

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# EU legal framework of public health

## ***The Treaty on the functioning of the European Union (Lisbon 2009):***

- The EU will be able to support, coordinate and supplement Member States in the quality and safety domain. Responsibility is with MS.
- Hard law for some topics in the quality and safety domain:
  - **Human blood and blood components (2002)**
  - **Donation and procedures around human tissues and cells (2004)**
  - **Human organs for transplantation (2010)**
  - **Patients' rights of cross-border healthcare (2011)**
  - **Pharmacovigilance and falsified medicinal products (2010, 2008)**
  - **Recognition of professional qualifications (2005)**



# EU value-based approach to health

**In 2006, Ministers came together to confirm the EU's commitment to overarching common values and principles such as:**

- universality,**
- access to good quality care,**
- equity,**
- solidarity.**



# Patient Safety Activities of the EU

- A working group on patient safety and quality of healthcare
  - EU Member States, EFTA, Council of Europe, WHO, OECD, European associations of patients, doctors, pharmacists, nurses, managers
- Projects
  - E.g. SIMPaTiE, EUNetPaS: EU network on patient safety 2007-2010
- Research Projects
  - E.g. Duque (quality in hospitals), Linnaeus (safety in primary care), Marquis (quality strategies), Handover, Helics (healthcare associated infections), etc.
- Legal tools
  - Council **Recommendation** on patient safety, including the prevention and control of HCAI (2009)
- **Joint Action on patient safety and quality of healthcare**  
(EU collaboration on patient safety and quality of healthcare)

# Quality Background at EU level

- COMAC (1990–1993), evaluating the concerted action programme on quality assurance in hospitals in a total of 262 hospitals in 15 European countries.
- ExPeRT (1996-1996), evaluating the use and development of external peer review models and to identify the main models used in the EU.
- ENQuaL (2003-2005), network to facilitate the exchange of knowledge and expertise among European countries.
- MARQuIS (2005-2008), to assess the value of different quality strategies, survey in 389 hospitals in 8 countries and audit in 89 hospitals.

# Background at EU level

- SIMPATIE (2005 -2007), 1st EU project on patient safety in 15 European countries; aimed to establish a common European set of vocabulary, indicators, internal and external instruments for improvement of safety in health care.
- EUNeTPaS ( 2007 – 2010), EU network for patient safety regarding culture; education in PS; reporting and learning systems; medication safety.



# Handover

**Def: verbal and non verbal communication during the patient transfer**

- UE HANDOVER FP-7, research project;
- Defining the variation in communication, culture and technology;
- Prospective, multi – cultural study (process mapping, interviews; questionnaires; focus groups; observation);
- Identification of barriers and facilitators in medical, social and technological context during patient handover;
- Defining how variation in handover leads to adverse events and near misses;
- Evaluation of tools and education programs in handover;
- Evaluation of the financial effectiveness in handovers
- Qualitative study: 222 professionals (150/72); 92 patients in 6 countries: Poland, The Netherlands, Sweden, Italy, United Kingdom, Spain.

„Education in handovers? It's like planting carrots on the moon...”



„Maybe it should be, that a doctor communicates with another doctor? And not that a sick patient has the only responsibility?”





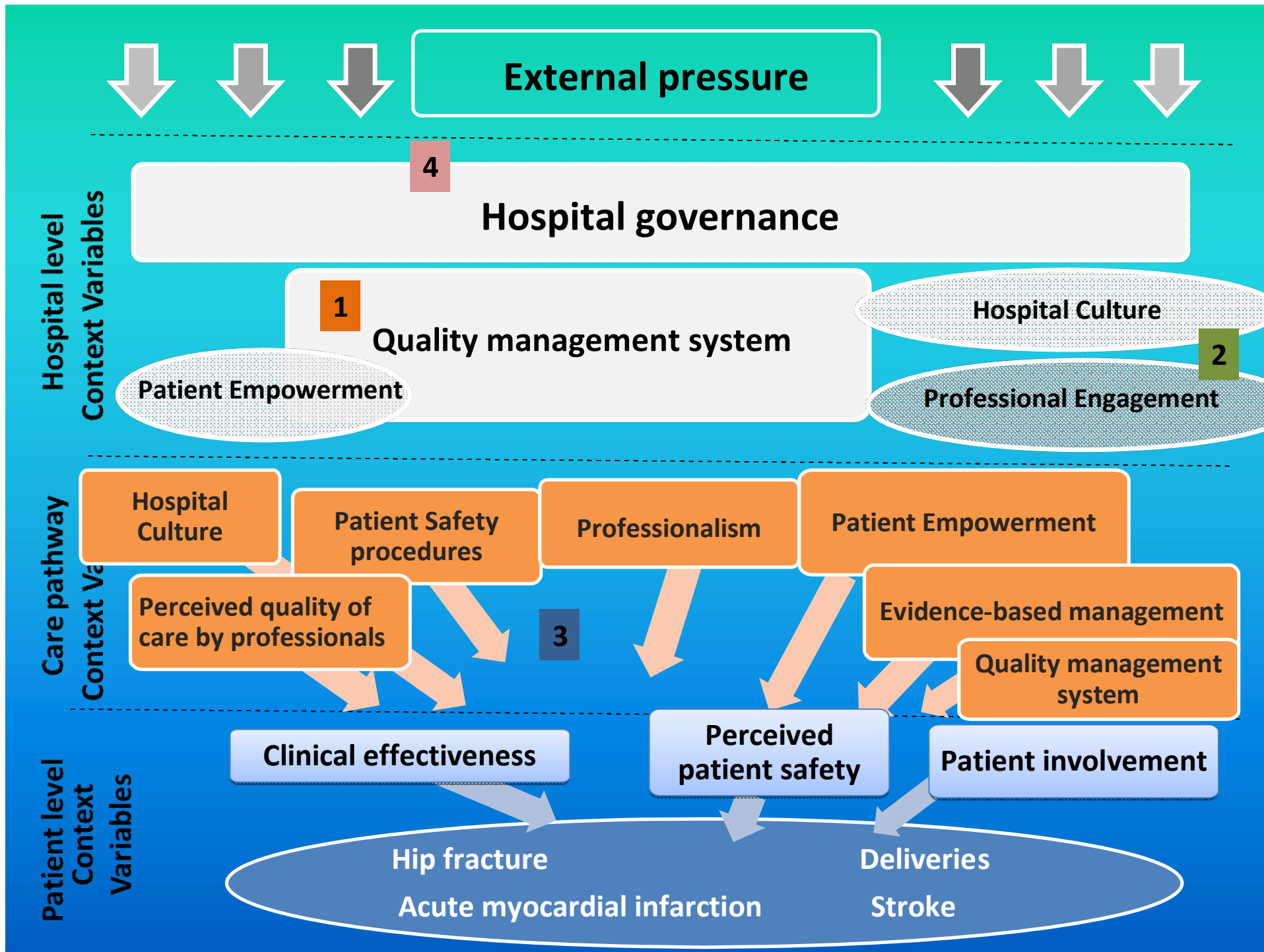
# **Deepening Our Understanding of Quality Improvement in Europe (DUQuE)**

**At European level, there is currently no comprehensive guidance for the hospitals on the development of their quality management systems.**

**Exploration of impact of quality improvement strategies on patient-level performance has not been performed at EU level.**

**DUQUE will aim at identifying the most effective quality and safety mechanisms.**

**This research will guide hospitals in developing, and purchasers in contracting hospital services**



# Council Recommendation on Patient Safety

## *Composed of two parts:*

- General patient safety issues (seven recommendations)
- Prevention and control of healthcare associated infections (two recommendations)

[http://ec.europa.eu/health/patient\\_safety/policy/index\\_en.htm](http://ec.europa.eu/health/patient_safety/policy/index_en.htm)

## **Council Recommendation:**

### ***Activities for Member States:***

- Patient safety policies, empowerment of patients, reporting and learning, education and training

### ***Actions for the EU with Member States***

- Classify, codify patient safety, share knowledge and good practices at EU level, promote research

### ***Healthcare associated infections (by ECDC)***

- Strategy for control and prevention of HCAI, mechanism for implementation

## Report on the implementation of the Council Recommendation<sup>1</sup>

- Based on a questionnaire to Member States
- The report is planned to be published in autumn 2012
- Some preliminary results:
  - *Few initiatives on **education in quality and patient safety** in MSs.*
  - *An **active role of patients in patient safety**, formalised in only few countries. This includes for example information for patients.*
  - *Almost all Member States have patient safety policies in place*
  - *Competent authorities in some of the Member States, partly on legal basis. Among major tasks: promoting best practices*
  - *Some Member States have patient safety standards in place and a majority of Member States would welcome EU guidelines on how to build and introduce standards*
  - *Routine reporting and learning of adverse events in some of the Member States.*
- Overall: it seems that although patient safety is embedded in public health policies in most of countries, there is still room for improvement, for example in the area of patient empowerment, education and patient safety standards.

<sup>1</sup> REPORT FROM THE COMMISSION TO THE COUNCIL on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare associated infections

## Report on the implementation of the Council Recommendation: lessons for the Joint Action?

- Along the lines of the report, the JA supports initiatives in Member States by:
  - *Sharing good practices*
  - *Cooperation on the strategies*
  - *Good practices in the area of patient-centeredness*
  - *JA may help to develop guidelines for patient safety standards*
  - *The network may help MS to further develop activities of national authorities*

## From patient safety to wider quality of healthcare

- Discussions in the **Council** Working Party on Public Health at **Senior Level** under the French and Spanish Presidencies
- **Reflection paper** on healthcare quality developed by the Commission and the working group
- Main discussion points:
  - Which areas of quality should and could be addressed at EU level?
  - How to ensure patient empowerment and involvement of health professionals?
- Some related EU activities:
  - Recognition of qualifications of health professionals; rare diseases; e-health network; cancer screening; patients' rights in cross-border healthcare, etc

## **Quality at the EU level – terms of reference of EU Working Group on Patient Safety and Quality of Care**

- **the creation of a patient-centred healthcare environment that respects the rights of patients and which treats all patients and their families with dignity;**
- **an increase in the quality of life of the patient at every stage of the patient pathway: including development of comparative data and quality improvement strategies in primary care, secondary care, mental healthcare, palliative care and disease prevention.**
- **an increase in patient involvement in healthcare: including the provision of clear and comprehensive information on efficacy and clinical outcomes; the building of health literacy; and support for self-management of chronic disease.**



# Directive on the application of patients' rights in cross-border healthcare

*The implementation of the Recommendation should be seen in a wider legislative context at EU level.*

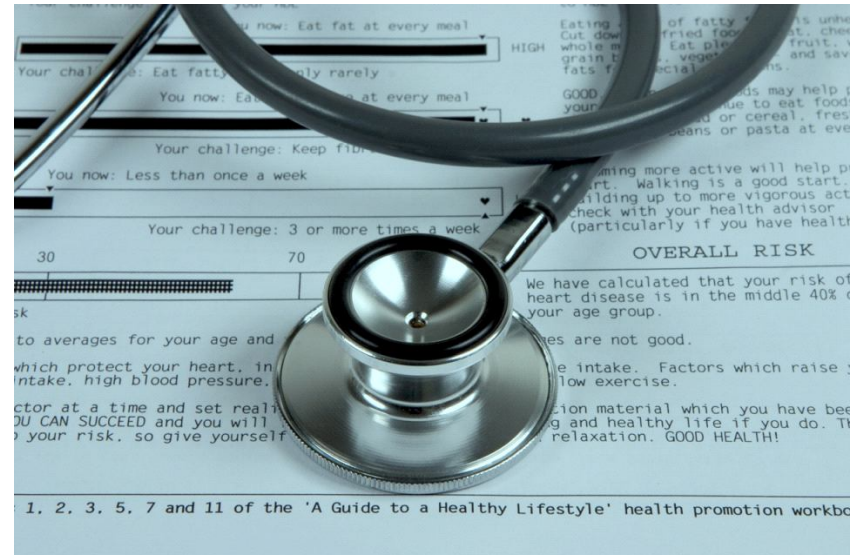


*The Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, also aims to promote:*

- ***Transparency for patients***  
Information about safety and quality regulations available for patients
- ***Information about healthcare providers***  
Refusal of prior authorisation if doubts over quality and safety of a healthcare provider
- ***Cooperation of Member States***  
On standards and guidelines on quality and safety

# Some challenges in the patients' rights Directive regarding quality and safety

- What kind of information is needed to conclude that there are no concerns about safety and quality of care provided at hospital level?
- How to ensure that mechanisms are in place to generate such information?
- How to ensure that information about safety and quality is available for competent authorities and patients?



# Patient empowerment

- Increasing attention for the role of the patient in healthcare
- Patient-centred healthcare included in the Commission Strategy “Together for Health” and in Council conclusions.
- Active role of the patient can promote patient safety and quality of healthcare
- Patients can have an active role in chronic disease management

- Recent EU events under Danish Presidency:

European conference on patient empowerment (12 April, 2012)

Informal Council (24 April, 2012), including a session on patient empowerment in the context of chronic disease management. It was concluded that patient empowerment should be a cornerstone of the EU approach in chronic diseases.

- The role of the patient is explicitly mentioned in the Joint Action

## **The role of professional organisations**

- *At national level, guidelines on quality and safety are often developed in close collaboration with professional organisations.*
- *Knowledge and the network of EU umbrella organisations for professionals should be used for improving healthcare delivery in the EU.*
- *Also related to the shaping of EU reference centres in the context of the Directive on cross-border healthcare.*

## The role of professional organisations

- *EU societies for medical specialists have been active in the development of:*
  - **Clinical guidelines (e.g. in the field of Neurology, orthopaedics, oncology, etc)**
  - **Curricula for medical specialists (e.g. the curriculum for general cardiology by the European Society for Cardiology, activities by CPME)**
- *The European federation for Nurses (EFN) have produced a position paper to highlight the need for quality and safety guidelines in the context of the development of reference centres in the EU.*

## Joint Action on Patient Safety and Quality of Healthcare

*Joint Action* means a collaboration between the Commission and Member States under co-financing by the Health Programme





An EU-level platform for collaboration and networking between:

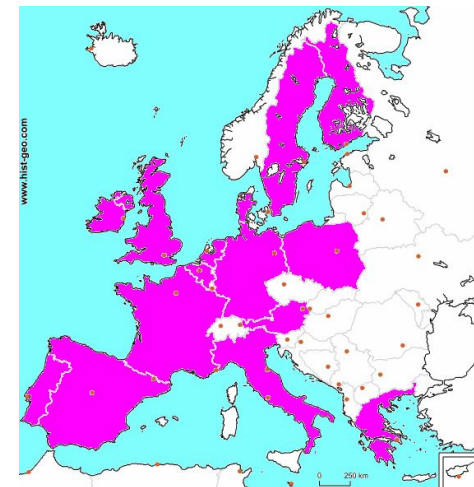
- 27 Member States
- International organisations
- European stakeholders in the field of healthcare (healthcare professionals, patients, institutions, scientists)





- National institutions on Patient Safety (PS):
  - Health care quality agencies
  - Dedicated PS agencies or departments
- Decision makers and financiers
- Healthcare professionals
- Patient representatives
- Research teams on PS

## National Platforms







# EUNetPaS Outcomes and Deliverables

Promote coherence at the EU level through recommendations and proposition of common tools

- **Culture measurement tool** and links to performance
- Guidelines for **education and training**
- Virtual library of European **reporting and learning systems**
- A mechanism for sharing **high priority PS issues and/or solutions** between all Member States
- Recommendation on **medication safety**
- An EU community of hospitals involved in PS

Create a sustainable European Network on PS

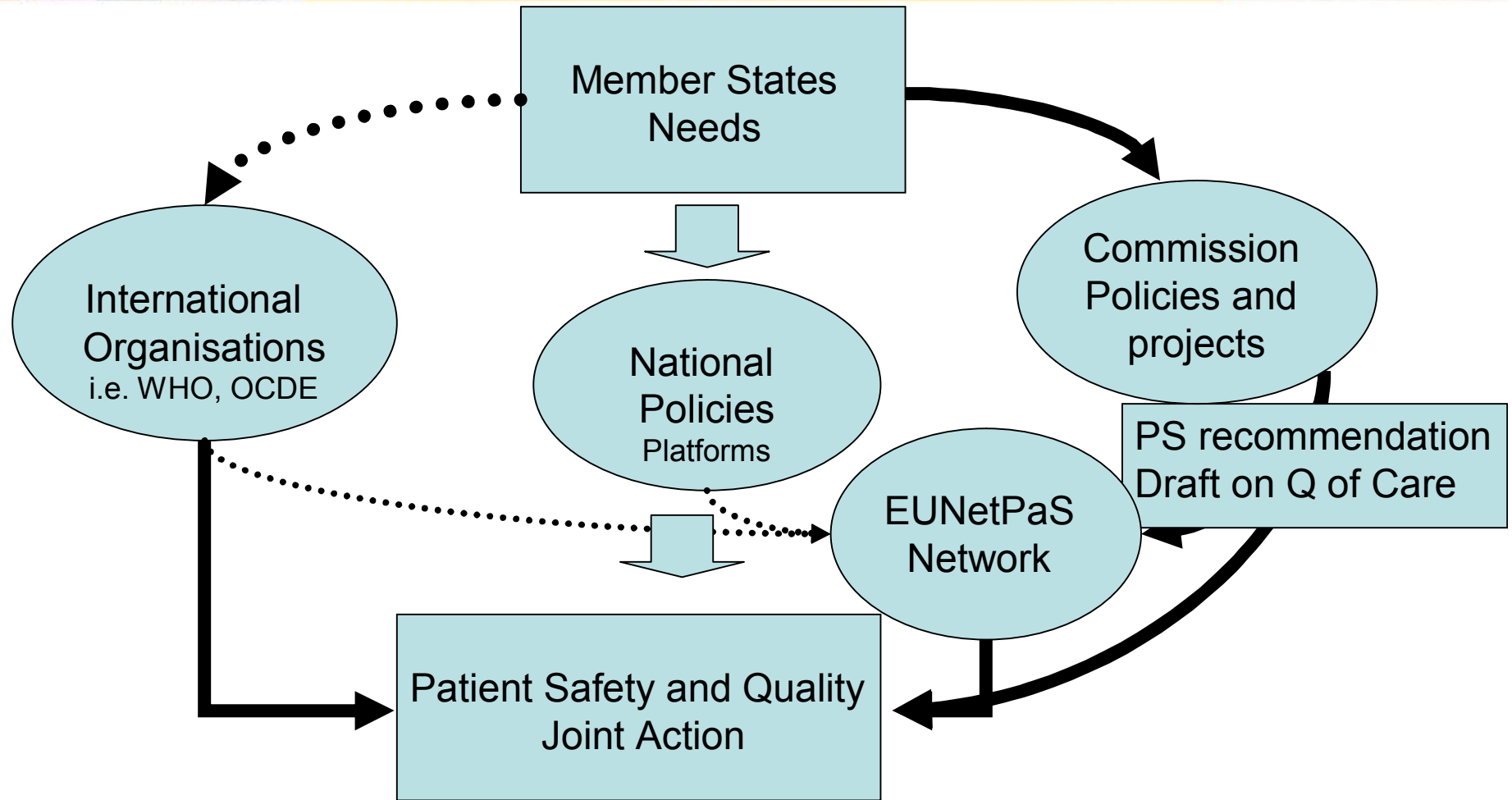
# Joint Action

## The Commission perspective

- Following the mandate of the Commission in the field of patient safety and quality of healthcare, the Joint Action aims to support developments in Member States
- This support focuses on:
  - The development of a sustainable EU network for cooperation, following the EUNetPaS initiative;
  - The implementation of (parts of) the Council Recommendation on patient safety;
  - Mutual learning by exchange of good practices, including implementation practices;
  - Explore quality of healthcare in the EU following the Council Working Party on Public Health at Senior Level.



# Joint Action in Patient Safety and Quality of Care



## Joint Action

- The Joint action is a special kind of project
  - It is initiated by the Commission, not an open call for proposals
  - The WG on patient safety and quality of healthcare contributed to shaping the objectives and content
  - It aims to catalyse the cooperation between Member States, with the aim to continue cooperation after the Joint Action.

The Joint Action on Patient Safety and Quality of Care is considered one of the major initiatives in patient safety in the following years.